Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. (Currently amended) A method of supplying starter cultures of consistent quality~~, the method~~ comprising the steps of: (i) providing an inoculum material comprising starter culture organism cells ~~a concentrate of starter culture organism cells~~, (ii) allowing the starter culture organism cells to propagate for a period of time sufficient to produce a desired amount of said starter culture organism cells; and (iii) harvesting the propagated cells to obtain a starter culture,

the method in step (i) improved by the steps of:

~~(ii)~~(a) concentrating said inoculum material of step (i) to obtain a concentrated stock inoculum material,

~~(iii)~~(b) dividing said concentrated inoculum material into subsets thereof, each of said subsets having a quality sufficient to inoculate a cultivation medium, and

~~(iv)~~(c) inoculating a subset of the stock inoculum material by direct, one step inoculation of said cultivation medium;

~~(v) allowing the starter culture organism cells to propagate for a period of time sufficient to produce a desired amount of said starter culture organism cells; and~~

~~(vi) harvesting the propagated cells to obtain a starter culture,~~

the method permitting, when steps (ii)~~(iv)~~ through (iii)~~(vi)~~ are repeated with another subset of the stock inoculum material, the supply of starter cultures having a consistent quality.

2. (Currently Amended) A method according to claim 1, wherein the ~~stock~~ inoculum material provided in step (i) is in quantities sufficient to inoculate at least 50,000 litres of cultivation medium.

3. (Currently Amended) A method according to claim 1, wherein the concentrated stock inoculum material provided in step (a)~~(i)~~ contains at least 10^8 CFU per g.

4. (Currently Amended) A method according to claim 1, wherein the subset of the stock inoculum material in step (c)~~(iv)~~ is directly inoculated in the cultivation medium at a rate of maximum 0.1%.

5. (Currently Amended) A method according to claim 1, wherein the amount of the subset of the stock inoculum material for direct inoculation of the cultivation medium in step (c)~~(iv)~~ provides a ratio of the CFU per g of cultivation medium, immediately after inoculation, relative to the CFU per g of the subset of the stock inoculum material being inoculated, said ratio being in the range from 1:100 to 1:100,000.

6. (Currently Amended) A method according to claim 1, wherein the cultivation medium immediately after the inoculation in step (c) ~~(iv)~~ contains a number of CFU per g of cultivation medium which is at least 10^5.

7. (Currently Amended) A method according to claim 1, wherein the cultivation medium in step (ii)~~(iv)~~ comprises any conventional medium used for propagation of microbial cells.

8. (Currently Amended) A method according to claim 1, wherein the ~~stock~~ inoculum material and/or the subset of the stock inoculum material is in a state selected from the group consisting of a liquid, frozen and dried state.

9. (Currently Amended) A method according to claim 8, wherein the frozen subset of the stock inoculum material is thawed before direct inoculation of the cultivation medium in step (c)~~(iv)~~.

10. (Currently Amended) A method according to claim 8, wherein the subset of the stock inoculum material is combined with an aqueous medium to obtain a suspension of the cells before direct inoculation of the cultivation medium in step (c)~~(iv)~~.

11. (Currently Amended) A method according to claim 1, wherein the direct inoculation of the cultivation medium in step (c)~~(iv)~~ is provided under aseptical conditions or under substantially aseptical conditions.

12. (Previously presented) A method according to claim 1, wherein the stock inoculum material is supplied in sealed enclosures.

13. (Original) A method according to claim 12, wherein the sealed enclosures are made of a flexible material selected from the group consisting of a polyolefin, a substituted olefin, a copolymer

of ethylene, a polypropylene, a polyethylene, a polyester, a polycarbonate, a polyamide, an acrylonitrile and a cellulose derivative.

14. (Original) A method according to claim 12, wherein the sealed enclosed are made of a flexible material comprising a metal foil.

15. (Original) A method according to claim 12, wherein the sealed enclosures have a cubic content of at least 0.01 litre.

16. (Previously presented) A method according to claim 12, wherein the sealed enclosures are supplied with outlet means for connection of the enclosure to a container comprising the cultivation medium, said outlet means permitting the concentrate of cells to be introduced substantially aseptically into the container to inoculate the cultivation medium with said concentrate of cells.

17. (Previously presented) A method according to claim 1, wherein the starter culture organism in step (i) originates from a species selected from the group consisting of a lactic acid bacterial species, a *Bifidobacterium* species, a *Propionibacterium* species, a *Staphylococcus* species, a *Micrococcus* species, a *Bacillus*, species, an *Actinomycetes* species, a *Corynebacterium* species, a *Brevibacterium* species, a *Pediococcus* species, a *Pseudomonas* species, a *Sphingomonas* species, a *Mycobacterium* species, a *Rhodococcus* species, an *Enterobacteriaceae* species, a fungal species and a yeast species. .

18. (Original) A method according to claim 17, wherein the lactic acid bacterial species is selected from the group consisting of *Lactococcus* spp., *Lactobacillus* spp., *Leuconostoc* spp., *Pediococcus* spp., *Oenococcus* spp. and *Streptococcus* spp.

19. (Currently Amended) A method according to claim 1, wherein the ~~stock~~ inoculum material in step (i) comprises at least two starter culture strains.

20. (Previously presented) A method according to claim 1, wherein the starter culture is a starter culture used in the food industry, feed industry or pharmaceutical industry.

21. (Previously presented) A method according to claim 1, wherein the starter culture is used for inoculation of milk which is further processed to obtain a dairy product, which is selected from the group consisting of cheese, yogurt, butter, inoculated sweet milk and a liquid fermented milk product.

22. (Previously presented) A method according to claim 1, wherein the cells being propagated in the cultivation medium express a desired gene product or produce a desired product.

23. (Original) A method according to claim 22, wherein the desired gene product is selected from the group consisting of enzymes, pharmaceutically active substances, polysaccharides and amino acids.

24. (Original) A method according to claim 22, wherein the desired product is selected from the group consisting of pigments, flavouring compounds, emulsifiers, vitamins, growth-stimulating compounds, food additives and feed additives.

25. (Previously presented) A method according to claim 7, wherein the medium comprises one or more single milk components.

26. (Previously presented) The method of claim 25, wherein one or more single milk components include skimmed milk.

27. (New) The method of claim 1, wherein steps (ii) through (iii) are repeated with another subset of the stock inoculum material and the supply of starter cultures resulting from each inoculation have a consistent quality.

REMARKS

Claims 1-11 and 19 are amended above. Claim 27 is added. With the proposed changes and additions, claims 1-27 will be pending. The present response changes claims in this application. A detailed listing of these revisions is presented, with an appropriate defined status identifier of all claims that are or were in the application, irrespective of whether the claim(s) remain under examination.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and these remarks.

Rejection Under 35 U.S.C. §112

The Office Action has rejected claims 1-26 as indefinite. Specifically, the Office Action states that claims 1, 2, 4, 5, 8, 9, 10, 12, and 19 and their dependants lack antecedent basis for reciting "the stock inoculum material." Applicant believes that the stated grounds for these rejections are obviated by the foregoing claim amendments.

Objections Under 35 U.S.C. §103

The subject matter of the various claims is commonly owned. Accordingly, there are no changes in inventor or invention dates of the claims.

The Office Action has rejected claims 1-7, 11, 17-22 and 24-26 as being obvious over Sing (U.S.P.N. 6,146,667) in view of Kosikowski (U.S.P.N. 5,098,721). The Office Action states that Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets, and cites to Kosikowski as teaching it is a common practice to divide mother cultures into subsets for use as a bulk starter. Applicant respectfully disagrees and traverses this rejection.

The present invention is to provide a method of supplying starter cultures with *consistent quality*, i.e. consistent with respect to metabolic activity and cell density within separately produced batches of the same starter culture. In this context, one should bear in mind that suppliers of commercial starter cultures for the dairy industry require large amounts of starter culture, and many commercial operations have propagation factories around the world. Having many different factories creates the problem of high variation of product quality both from batch to batch and also between factories and plants within the company. This variation was caused using traditional method because each batch was produced by a stepwise or successive propagation, starting from a generally small

amount of stock inoculum material (mother culture), which involved 2 to 4 propagation steps using increasing volumes of cultivation medium in order to obtain a sufficient amount of inoculum material to inoculate the final cultivation medium for the production of the commercial starter culture.

As described in the present specification on page 2, each step in this procedure involved a serious risk of contamination of the inoculum material with undesired organisms, which is one of the reasons for a variation with respect to metabolic activity and cell density between separately produced batches of the same commercial starter culture. Thus, a great percentage of the produced batches had to be discarded because of unsatisfactory quality which resulted in an economic loss for the company.

Thus, the present invention solves the industrial need for an improved procedure for inoculation of the final inoculum medium, i.e. the "cultivation medium" of step (c) in claim 1, at the propagation plants as described on pages 2-3 in the specification.

The solution to this long felt need was summarized in the amendment of 18 April 2002, filed in response to the Office Action dated 18 December 2001. In this response, Applicant illustrated that the advantages of the present invention is that it is possible to provide a central production of a concentrated first stock inoculation material (SIM1), i.e. step (a) in claim 1. This first stock inoculation material (SIM1) is subsequently divided into several fractions (subsets, starter cultures SIM1a, SIM1b, SIM1c, etc., i.e. step (b) in claim 1). Then the subsets may be transported to different individual propagation factories to be used as an inoculum (starter culture) for different productions of desired commercial starter cultures which all will have substantially the same quality because they originate from the same, central-produced stock inoculation material (SIM1) and do not undergo a stepwise or successive propagation, i.e. they are produced by a "one-step" procedure.

The unexpected advantage of the method step of claim 1 is shown in Table 1.1 in the present specification. It was found that the variation between the quality of commercial starter cultures produced according to the invention was low (deviation: 8.6 (metabolic activity) and 6.35 (cell number)) compared to the variation between the quality of starter cultures using the conventional method (deviation 22.61 (metabolic activity and 23.61 (cell number)).

A further example of the advantage of the method according to the present invention is shown in the enclosed Declaration of Boerge Kringelum. The Declaration evidence that the production cost for the production of commercial starter cultures can be substantially reduced when

using the method of the invention, because the stepwise propagation of the cells is omitted at the individual propagation factories, which results in a more consistent quality and thus fewer batches have to be discarded due to unsatisfactory quality.

The prior art cited in the Office Action in fact teaches away from the invention of claim 1. For example, Kosikowski describes that the dairy plant uses "a mother culture which periodically is transferred, usually daily, into a plurality of growth medium containers *with the best resulting cultures selected* for making a larger volume of starter e.g. bulk starter." (Col 1). The present invention avoids the stepwise or successive propagation of a microbial culture taught in Kosikowski, which results in numerous problems as noted above. The claimed invention permits each of the subsets of concentrated stock inoculum to be of a sufficient quality for use to inoculate a cultivation medium. *See* Claim 1, step (b) and Claim 27. This results in starter cultures having consistent qualities between batches. *See* Pages 4, 8, 9, and Table 1.1 of specification, Kringelum Declaration, and Claims 1, step (b) and 27.

The present invention also is concerned with *a beneficial production method* of a commercial starter culture, unlike Sing and Kosikowski which are concerned with *the effective use* of said commercial starter culture. The cited prior art documents, when viewed in their entirety, are not concerned with providing a beneficial inoculation procedure at the propagation factory as claimed by Applicant. Instead, the art is concerned with how to improve the starter culture in order to speed up the preparation of the bulk starter at the dairy. Indeed, no one, including those skilled in the art, combined these two teaching in order to reach a more beneficial method or procedure because Sing and Kosikowski are not concerned with the *production* of a commercial starter culture, but are concerned with how to improve the *use* of a starter culture at the dairy. Despite the long felt need for a more beneficial and economic procedure of producing a commercial starter culture at the factory/supplier stage, nobody has ever before found or realized that concentrating and dividing the inoculum at the propagation factory would be the key to a beneficial production method of commercial starter cultures, even though this would result in an economic profit. *See* Kringelum Declaration.

Applicant submits that no permutation of Sing and Kosikowski with the other cited documents (Czulak et al., Lizak, Vandenbergh et al., Matsumiya et al. or Rimler et al.) renders claim 1 obvious, within the meaning of Section 103. All of the dependant claims are believed to be allowable in view of the currently amended claim 1.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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